

REMARKS

Although not specifically stated in the section of the Office Action entitled Election/Restrictions, the Examiner made a new restriction requirement by rejoining species o) and q) of Part 1 to elected species c) of Part 1. Hence, Applicant has the right to traverse such new restriction requirement and does so below.

This new restriction requirement marks the fourth time the Examiner has made a different restriction requirement in this application. The initial restriction requirement of September 15, 2003 was vacated and replaced with a new restriction requirement on November 19, 2003. Such restriction requirement was replaced by another new restriction requirement on February 24, 2004 because of an apparent misunderstanding of the term "organic." A fourth restriction requirement was made on June 3, 2004, on the basis of a newly provided interpretation of "living organism." Such interpretation was made for the first time and is at odds with the interpretation intended by Applicant's election of March 3, 2004. More than three years after submitting a response on the merits, Applicant is now faced with attempting to resolve formal issues rather than returning to issues related to the merits of his claimed invention.

The latest restriction requirement, for the first time, was interpreted by the Examiner to exclude multifactorial and non-specific living organisms and, in effect, results in the term "living organism" being essentially restricted to bacteria and virus. Following such interpretation, the Examiner made an action on the merits regarding such improperly limited types of living organisms.

Applicant hereby traverses the new restriction requirement on the grounds that its prior election of living organisms obviously was intended to and does, in fact, include multifactorial and non-specific living organisms, such as stem cells. Clearly, the previous introduction of new claims 376-381 indicated that Applicant intended to prosecute claims directed to growth factors

comprising multifactorial and non-specific living organisms. Regarding multifactorial and non-specific growth factors, Applicant respectfully directs the Examiner's attention to page 21, lines 14 and 15 and to page 37, line 19 of the instant specification. It is clearly disclosed, at page 21, lines 14 and 15, that growth factors can be multifactorial and non-specific and that multifactorial and non-specific cells, as set forth at page 37, line 19, are contemplated.

As the Examiner well knows, cells are living organisms. That stem cells are clonogenic and that clones are living organisms are such well-established biological tenets, that official notice should be taken of these facts. In any event, clonogenic means the cells generate identical copies of themselves. Cloning occurs and/or can occur *in vivo*, *in vitro*, and *ex vivo*. Based on the aforesaid information, it is an irrefutable fact that cells, including stem cells, are living organisms. Please see the NIH Glossary definition of clone: "Clone -- a line of cells that is genetically identical to the originating cell; in this case, a stem cell" (attached hereto as Exhibit I); the Commonwealth Government of Australia definition of cloning: "Cloning -- cloning makes use of technology to create an exact genetic copy of a living organism" (attached hereto as Exhibit II); and the About Biotech/Biomedical definition of cloning: "Cloning -- making a genetically identical copy of a living organism" (attached hereto as Exhibit III).

It is clear that Applicant's specification describes the term "multifactorial and non-specific" to characterize a type of growth factor rather than causes, effects, and processes, as interpreted by the Examiner. The outstanding Office Action is incomplete because the Examiner's interpretation was erroneous and is inconsistent with Applicant's intended election. Applicant requests reconsideration of the newly formulated restriction requirement and an action on the merits of its elected invention, as embodied by newly presented claims 382-388.

In view of the numerous altered restriction requirements, which have contributed to the more than three-year delay in obtaining an action on the merits, and the consequent significant erosion in term, Applicant believes that there is no viable option except to cancel claims 192-381 and present new claims 382-388 in an effort to eliminate the above-mentioned restriction issues and to thereby facilitate an action on the merits of the intended elected invention. Claims 192-381 are cancelled without prejudice to including the same or similar claims in a divisional, continuation, or continuation-in-part application. Applicant believes that he has been forced to take such course of action because of the above-mentioned term erosion caused by, what he considers to be, inordinate delays by the PTO in the prosecution of the instant application. Applicant points out that the cancellation of claims 192-381 was made solely for procedural and term length considerations not related to the patentability of such claims, and thus no abandonment of the subject matter of these claims was intended or made by such cancellation.

The title of the specification has been amended to be more clearly indicative of the elected invention to which the claims are directed.

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374, and 376-381 are objected to because these claims were alleged to read on non-elected inventions. Such objection is obviated because all of the above claims have been canceled by the instant amendment and replaced by claims directed to Applicant's intended elected invention.

Claims 216, 217, 277, 278, 338, 339, 340, 340, and 376-381 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. While the cancellation of these claims serves to obviate the rejection, it is pointed out that several of the newly presented claims contain the term "multifactorial and non-specific." It is submitted that the rejection should not be

repeated for such claims because Applicant has used the term “multifactorial and non-specific” in the specification to characterize living organisms, such as stem cells -- not to describe causes, effects, and processes as incorrectly premised by the Examiner. This point has been addressed previously in this Amendment and need not be repeated here.

Claims 192, 193, 195-199, 211, 213-225, 227, 243-251, 253, 254, 256-260, 272, 274-286, 288, 304-312, 314, 315, 317-321, 333, 335-348, 350, 366-374, and 376-381 were rejected under 35 U.S.C. §101 and 112. This rejection is premised on what Applicant believes to be the Examiner’s incorrect and improper interpretation of the term “living organism,” i.e., that such term is limited to bacteria and virus and does not include cells. The instant rejection does not apply to newly submitted claims 382-388 because these claims conform to the invention clearly intended to be elected by Applicant. Accordingly, Applicant believes that the outstanding rejection is not relevant to claims 382-388 and should be withdrawn by the Examiner.

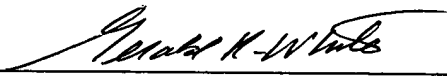
As also succinctly pointed out above, the outstanding Office Action constitutes the first action on the merits by the PTO since Applicant’s response filed February 15, 2001. Moreover, the three-year term extension guarantee does not apply to the instant application. Thus, Applicant has already been severely prejudiced in term length by the long and inordinate delay between the February 15, 2001 response and the Office Action of June 3, 2004. Applicant believes that, especially in view of the above factual situation, that he is entitled to a prompt and complete action on the merits of the invention that was clearly intended to be elected in the response filed March 3, 2004. Such elected invention is embodied by newly presented claims 382-388.

Applicant believes that the newly presented claims are consistent with the previously elected invention, are in condition for examination, and an early action on the merits of such claims is respectfully requested.

Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated. A phone call could help prevent future misunderstandings of the type mentioned above.

Respectfully submitted,

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